

REMARKS

Before the amendment made herein claims 71 and 72 were pending in the subject application. Claims 73 and 74 have been added herein. Accordingly, after entry of the amendment made herein, claims 71 to 74 will be pending.

Applicant wishes to thank the Examiner, as well as Examiner Achutumurthy, for interviewing this case on March 8, 2005.

I. Regarding the amendment.

New claims 73 and 74 precisely track current claims 71 and 72, respectively, with one exception. Instead of reciting that "none of said somatic mammalian cells in said preparation is genetically modified to express heparanase," as is provided in claim 71, new claim 73 instead recites that "said purified mammalian heparanase enzyme is added to said preparation." Support for this recitation can be found in the specification, for example, at pages 48, lines 18-22, which describes **adding** heparanase to a preparation of cells.

Because the new claims are fully supported by the specification, no issue of new matter arises.

II. Written Description Rejection.

Claims 71 and 72 are rejected under 35 U.S.C. sec. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant respectfully traverses the rejection.

- A. **The subject application necessarily shows that exemplified cells are not genetically modified to express heparanase. Moreover, the Examiner has not met his burden of explaining why this disclosure is not adequate.**

In an Advisory Action mailed February 2, 2005, the Examiner acknowledges that claim 71 recites that none of said cells is genetically modified **to express heparanase**. The Examiner also seems to acknowledge in the Advisory Action the general concept of inherent or implied disclosure to satisfy the written description requirement.

As stated in the previous response, the examples in the subject application describe a cell preparation to which heparanase **is added**. See, for example, Application at pages 48, lines 18-22, which describes **adding** heparanase to a preparation of bone marrow stromal cells. In view of this disclosure, the skilled artisan reading the application would **necessarily** know that such exemplified cells have **not** been genetically modified to express heparanase. **Seeing from the disclosure in the specification that heparanase is being added to a cell preparation, there would be no**

reason whatsoever to genetically engineer the cells to express heparanase. The skilled artisan would clearly understand this.

- B. To satisfy the written description requirement, disclosure can be implicit or inherent. This is a classic example of such disclosure. The Examiner has not provided any explanation whatsoever to the contrary.**

The MPEP provides that the disclosure to support a claim can be **implicit or inherent**. MPEP sec. 2163(I)(B). Moreover, the **Examiner** has the **burden** of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Sec. 2163(II)(A).

Reading the subject application, the skilled artisan would clearly know that it implicitly describes cells that are not genetically modified to express heparanase. Therefore, claim 71 is adequately supported by the written description of the application. Furthermore, the Examiner has **still** not provided reasoning or an explanation why this implicit disclosure is not sufficient and, therefore, has not met his burden.

Accordingly, Applicant respectfully requests that this rejection be withdrawn. Should this rejection not be withdrawn, Applicant again respectfully requests that the Examiner meet his required burden and provide an explanation why the implicit disclosure in the subject application is not sufficient for fulfilling the written description requirement of pending claims 71 and 72.

Applicant notes that, in the Advisory Action, the Examiner states in a conclusory fashion that the above-cited disclosure is not considered implicit. With due respect, this does not meet the Examiner's required burden to sustain this rejection. Rather, the Examiner must explain why the skilled artisan, being taught that heparanase is being added to a cell preparation, would not implicitly or inherently understand that these cells have not been genetically engineered to express heparanase. The Examiner has not provided any such explanation and, therefore, this rejection should be withdrawn.

To reiterate Applicant's position, there is **no logical reason** to genetically engineer cells to express heparanase when heparanase is **already being added** to this preparation of cells. This is an absolutely clear example of implied or inherent disclosure and, therefore, meets the requirements of written description under the law. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

App. Ser. No. 09/260,037

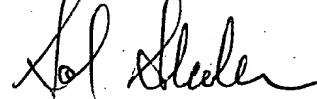
Response to Action mailed November 12, 2004

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CONCLUSION

All of the issues raised in the final Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore, Applicant respectfully requests a Notice of Allowance to this effect.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Sol Sheinbein', written over a horizontal line.

Sol Sheinbein

Registration No. 25,457

Date: March 9, 2005

Enc:

Request for Continued Examination

Request for One-month Extension of Time